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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,815	05/11/2005	Doris Kretzschmar	P67566US1	4915

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EXAMINER
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GEMENIANO, MALOU C

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/501,815	KRETZSCHMAR ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Malou C. Gemeniano	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-11, drawn to a non-human transgenic animal with a modified version of B-amyloid protein precursor like protein.

Group 2, claim(s) 12,15 and 16, drawn to a method to identify a modulator affecting lipid metabolism.

Group 3, claim 13, drawn a method to identify a modulator which affects neurodegenerative phenotype

Group 4, claim 14, drawn a method to identify a modulator which affects processing of an amyloid precursor protein.

Group 5, claim 17, drawn a method to identify whether a gene or a mutant thereof is capable of modulating a phenotype related to lipid metabolism and/or neurodegeneration.

If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

The inventions listed as Groups 1-5 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of Group I is drawn to a non-human transgenic animal with a modified version of B-amyloid protein precursor like protein. Groups 2-5 are drawn to

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multiple distinct methods of use and multiple distinct products that do not share the same inventive concept with each other as well as the product of Group 1. The claimed inventions of Groups 2-5 recite distinct materials and/or method steps that are do not require the claimed invention of Group 1, and thus have their own technical features, e.g. a method to identify a modulator affecting lipid metabolism (Group 2), drawn a method to identify a modulator which affects neurodegenerative phenotype (Group 3), drawn a method to identify a modulator which affects processing of an amyloid precursor protein (Group 4) and drawn a method to identify whether a gene or a mutant thereof is capable of modulating a phenotype related to lipid metabolism and/or neurodegeneration (Group 5). Further, each of the groups has a technical feature not required for the other groups. For example, a method to identify a modulator affecting lipid metabolism of Group 2 is not required for the method to identify a modulator which affects processing of an amyloid precursor protein 4. The Groups are also distinct inventions because the method inventions can be performed using other and materially distinct products, such as a cell where the method can be done in vitro or a non-transgenic animal that has naturally occurring modified version of B-amyloid protein precursor like protein. In addition, transgenic animal can be used for processes other than the methods of the claimed inventions, such as in breeding with other animals. Furthermore, because these methods have such divergent purposes and functions as well as effects, the search for one method would not be co-extensive with another method. For example, Group 4 is drawn a method to identify a modulator which affects processing of an amyloid precursor protein while Group3 is drawn to a method to identify a modulator which affects neurodegenerative phenotype. In this instant, these methods uses different starting material as well have different effects and objective. The scope of group 8 does not over lap with the scope of group 4; therefore, their searches would not be co-extensive and would be undue burden to perform a search the products and methods group together or any combination thereof.

Each invention is directed to a distinct goal, which comprises the use of separate products or methods in order to achieve its respective and intended objective. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups 1 to 13

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do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

In addition, this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Applicant is required to further elect from the following species of identifiable phenotypes as recited in claim 7: a) phenotype related to lipid metabolism b) phenotype related to neurodegenerative disease c) phenotype related to neurodegenerative disease and a phenotype related to lipid metabolism.

Applicant is required to further elect from the following species of gene expression as recited in claims 8, 9 and 10: a) gene encodes for an amyloid precursor protein b) gene encodes for modified version of the gene coding for beta amyloid protein precursor-like (Appl) protein c) gene encodes for a deletion of beta amyloid protein precursor-like (Appl) protein d) gene encodes for a partial-deletion of beta amyloid protein precursor-like (Appl) protein.

Applicant is required to further elect from the following species of mutagenesis as recited in claim 4: a) transposon insertion mutagenesis b) chemical mutagenesis

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 7 and claims dependent therefrom correspond to all species list above.

The following claim(s) are generic: claim 6

Claims 8,9 and 10 and claims dependent therefrom correspond to all species list above.

The following claim(s) are generic: claim 1

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features.

Applicant is advised that the reply for this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malou C. Gemeniano whose telephone number is 571-272-6451. The examiner can normally be reached on 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is (571)-272-0532.

For all other customer support, please call the USPTO Call Center (UCC) at (800)-786-9199.

Malou C. Gemeniano, Ph.D  
Examiner, USPTO, AU 1632



**DAVE TRONG NGUYEN**  
**SUPERVISORY PATENT EXAMINER**